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SCR PHARMATOP

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

CADENCE PHARMACEUTICALS,
INC. and SCR PHARMATOP,

Plaintiffs,

v.

FRESENIUS KABI USA, LLC,

Defendant.

AND RELATED COUNTERCLAIMS

CASE NO. 13-CV-00139 DMS (MDD)

**EXHIBIT 2 TO THE
DECLARATION OF STEPHEN P.
SWINTON IN SUPPORT OF
PLAINTIFFS' RESPONSE TO
FRESENIUS'S OBJECTION TO
MAGISTRATE JUDGE DEMBIN'S
ORDER STRIKING THE MARAIS
REPORT**

EXHIBIT 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

BEFORE HONORABLE DANA M. SABRAW, JUDGE PRESIDING

_____)	
CADENCE PHARMACEUTICALS, INC., ET AL.,)	
)	CASE NO. 13CV0139-DMS
PLAINTIFF,)	
)	
VS.)	
)	SAN DIEGO, CALIFORNIA
FRESENIUS KABI USA, LLC,)	NOVEMBER 4, 2013
)	9:00 A.M. CALENDAR
DEFENDANT.)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS

CLAIM CONSTRUCTION HEARING

REPORTED BY:	LEE ANN PENCE, OFFICIAL COURT REPORTER
	UNITED STATES COURTHOUSE
	333 WEST BROADWAY ROOM 1393
	SAN DIEGO, CALIFORNIA 92101

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ALSO PRESENT:

HAZEL AKER, ESQ.

1 FOREST. I THINK, ALTHOUGH IN VERY SIMPLE NONCHEMICAL TERMS,
2 IS REALLY THE SUBSTANCE OF WHAT THE DEFENDANTS ARE ARGUING.
3 THEY ARE ARGUING TWO THINGS THAT WE THINK ARE WRONG IN THE
4 INTRINSIC EVIDENCE, WRONG IN THE SCIENCE.

5 THEY ARGUE, FIRST, THAT A BUFFER CAN ONLY BE A
6 BUFFER IF IT ACTUALLY ACTS ON AN EXOGENOUS ACID OR BASE,
7 THEREFORE A BUFFER -- A BUFFERING AGENT THAT MIGHT BE A
8 BUFFERING AGENT IN SOME OTHER SAMPLE OF THE SAME FORMULATION
9 OR --

10 (ALARM TEST)

11 **THE COURT:** ALL RIGHT.

12 **MR. SWINTON:** OR THE OTHER ALTERNATIVE, EVEN IN A
13 BUFFERING -- THE SAME AGENT IN ANOTHER FORMULATION WAS
14 ADMITTEDLY A BUFFERING AGENT IF IT IS NOT ACTUALLY BEING --
15 ACTING UPON SOME ACID OR BASE THAT MAKES ITS WAY INTO THE
16 FORMULATION THEN IT IS NOT A BUFFER.

17 WE DON'T BELIEVE THAT IS SUPPORTED BY THE
18 SPECIFICATION OR CHEMISTRY.

19 AND THEN SECONDLY THEY ARGUE THAT -- AND I WILL
20 ADDRESS BOTH OF THESE. THEY ARGUE THAT IN ORDER TO BE A
21 BUFFER A BUFFERING AGENT MUST HOLD A PRECISE PH, THAT IT MUST
22 MAINTAIN A PRECISE PH. AND, AS I WILL SHOW, EVEN THE
23 DICTIONARY DEFINITIONS UPON WHICH THEY RELY DISPUTE THAT
24 CONCEPT.

25 SO AGAIN, THE CLAIM LANGUAGE THAT WE HAVE IN FRONT

1 OF US MERELY REFERS TO A BUFFERING AGENT. THE SPECIFICATION
2 DOES NOT HAVE ANY LIMITING LANGUAGE THAT WOULD PROVIDE ANY
3 BASIS FOR THE DEFENDANTS TO READ IN THE LIMITATIONS THAT THEY
4 OFFER. PRETTY STRAIGHTFORWARD.

5 AND, INDEED, IN THE SPECIFICATION IS THE -- IS AT
6 LEAST THE FIRST INDICATION, AS WE WILL SEE IN THE CLAIMS, THAT
7 THE PATENTEES ANTICIPATED THAT THE BUFFERED RANGE FOR THE
8 CLAIMED FORMULATIONS WOULD RUN ANYWHERE FROM 4 TO 8, NOT BEING
9 HELD AT A SPECIFIC LEVEL AT ALL.

10 NOW, HERE IS THE DEFENDANTS' DICTIONARY DEFINITION
11 THAT THEY PROFFERED FOR THIS -- FOR THE SUPPORT FOR THEIRS IS,
12 I THINK, THE BEST EVIDENCE THAT THE IDEA THAT A BUFFERING
13 AGENT HAS TO RESIST ALL CHANGE IN PH IS IMPOSSIBLE IN A
14 CHEMICAL SENSE AND NOT REALISTIC FROM THE REAL WORLD SENSE.
15 AND, IN FACT, THAT IS WHAT IS REFLECTED IN THEIR DEFINITION.

16 THEIR CITED DICTIONARY DEFINITION FROM STEDMAN'S
17 MEDICAL DICTIONARY FOR BUFFER HAS THIS STATEMENT: A MIXTURE
18 OF AN ACID AND ITS CONJUGATE BASE --

19 AND I WILL SKIP OVER THE CHEMISTRY.

20 -- THAT, WHEN PRESENT IN A SOLUTION, REDUCES ANY
21 CHANGES IN PH THAT WOULD OTHERWISE OCCUR IN THE SOLUTION.

22 WE DIDN'T MAKE THAT UP. WE BELIEVE THAT IS
23 ACCURATE. A BUFFERING AGENT WILL REDUCE CHANGES IN PH BUT IT
24 DOES NOT GUARANTEE THAT THERE WON'T BE ANY CHANGES IN PH. AND
25 YET THAT IS PRECISELY THE CRUX OF THE ARGUMENT THAT THEY MAKE,

1 **MR. SWINTON:** AGAIN, OUR INTENT BY THE "CAN" TO BE
2 ADDED TO JUDGE STARK'S DEFINITION WAS NOT INTENDED TO UPSET
3 HIS DEFINITION OR TO EXPAND WHAT WE BELIEVE TO BE, AND JUDGE
4 STARK RULED TO BE, THE ESSENCE OF A BUFFERING AGENT AS CLAIMED
5 IN THESE PATENTS.

6 AND AS A RESULT, AS I SAID, WE WOULDN'T WALK OUT OF
7 THE COURTROOM THINKING JUSTICE HADN'T BEEN DONE IF WE KEPT
8 THAT. WE JUST KNOW, FROM THE FIGHTS WE SAW IN DELAWARE, THAT
9 THERE WERE -- THESE SAME ARGUMENTS WILL RECIRCULATE HERE
10 UNLESS WE ADOPT THIS SLIGHT MODIFICATION THAT STILL FINDS
11 FAVOR WITH JUDGE STARK'S RULING.

12 **THE COURT:** THAT WOULD BROADEN THE CLAIM, WOULD IT
13 NOT?

14 **MR. SWINTON:** I DON'T THINK IT BROADENS THE CLAIM.
15 IN FACT, MY FINAL SLIDE SHOWS WHY IT DOESN'T BROADEN THE
16 CLAIM.

17 THAT IS, AGAIN, IT IS NOT A QUESTION -- THIS IS AN
18 EXAMPLE OF CLAIM 3 FROM THE PATENT IN WHICH THE PATENTEES MADE
19 CLEAR THAT THE -- AT LEAST UNDER CLAIM 4 THE PH RANGE COULD
20 RUN FROM 4 TO 8 ON THE PH SCALE FOR THE CLAIMED FORMULATION.
21 AS A DEPENDENT CLAIM ON WHAT CLAIM 1 CLAIMED AS A BUFFERING
22 AGENT IN THE FIRST PLACE, THERE IS NOTHING HERE THAT SAYS THE
23 BUFFERING AGENT HAS TO HOLD THE PH AT A PARTICULAR POINT. IN
24 FACT, THE ESSENCE OF THE RANGE THERE, WE THINK, ANTICIPATES
25 THAT. SO THEREFORE IT DOESN'T BROADEN THE CLAIM TO MERELY

1 INDICATE THAT IT CAN HELP RESIST CHANGE AS OPPOSED TO HAVING
2 TO ACTUALLY RESIST CHANGE IN THOSE CASES WHERE THERE MAY NOT
3 BE AN ACID OR A BASE ADMITTED INTO THE FORMULATION AFTER IT IS
4 MADE.

5 **THE COURT:** THANK YOU.

6 **MR. SWINTON:** THANK YOU.

7 **THE COURT:** ALL RIGHT.

8 **MR. BENNETT.**

9 **MR. BENNETT:** YOUR HONOR, I AM BRIEFLY GOING TO
10 ADDRESS THIS ISSUE OF THE ADDITION OF "CAN" BECAUSE, AS THE
11 FOCUS OF MR. SWINTON'S PRESENTATION, I DO THINK IT IS A
12 PROBLEM. I DO THINK IT BROADENS THE CLAIM.

13 AS WE STATED IN OUR BRIEFING, YOU KNOW, ONE PROBLEM
14 HERE IS THAT IT REALLY OPENS THE DOOR TO THE POSSIBILITY OF
15 THEM ARGUING THAT EVEN A SUBSTANCE THAT HAS A THEORETICAL
16 IMPACT IN RESISTING PH, EVEN IF THERE IS NO SCIENTIFIC PROOF
17 THAT IT DOES, COULD INFRINGE THE CLAIM.

18 AND IT ALSO OPENS THE DOOR OF IT RESISTING, REALLY,
19 IN FINDING INFRINGEMENT IF THERE IS ANY CHANGE -- ANY
20 RESISTANCE TO CHANGE OF PH ANYWHERE ON THE PH SCALE WHICH, FOR
21 REASONS THAT I WILL EXPLAIN IN A MINUTE, REALLY DON'T MAKE
22 SENSE WHEN YOU READ THIS PATENT AS A WHOLE.

23 NOW, A BRIEF BIT OF CONTEXT.

24 AS YOU KNOW, YOUR HONOR, WE ARE CONTESTING IN THIS
25 CASE THAT OUR PRODUCT DOES NOT CONTAIN A BUFFERING AGENT. AND